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EXAMINER	
LUM, LEON YUN BON	
ART UNIT	**PAPER NUMBER**
1641	

DATE MAILED: 12/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/988,728	SELVAN, GOWRI PYAPALI	
	Examiner	Art Unit	
	Leon Y Lum	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 October 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22,30 and 31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22,30 and 31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 October 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The amendment filed 21 October 2004 is acknowledged and has been entered.

Specification

2. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: In claim 13, line 2, the phrase "determine a cell concentration" is not disclosed in the specification.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1-9, 12-15, 17-22, and 30-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sheppard, Jr. et al (USP 6,143,247) in view of Sizto et al (USP 5, 962, 238).

In the instant claims, Sheppard, Jr. et al reference teaches a method of conducting an assay, the method comprising providing a sample of cells in a chamber in a disc, the chamber including at least one capture zone with a capture agent, loading the disc into an optical reader, rotating the disc so as to separate different cell types into different capture zones, directing an incident beam of electromagnetic radiation to the capture zone, detecting a beam of electromagnetic radiation formed after interacting with the disc as the capture zone, converting the detected beam into an output signal, and analyzing the output signal to extract therefrom information relating to the number

of cells captured at the capture zone, counting captured cells in each of the capture zones, and providing an output including the counts, by disclosing a method where a sample is applied to a detection or cell accumulation chamber of a platform (column 14, lines 6-7), wherein the term "platform" is intended to encompass any solid support structure providing a surface or comprising a chamber that can be treated to comprise a specific binding reagent (column 10, lines 15-18), and that the surface or detection chamber can be treated to provide a two-dimensional array or pattern, wherein certain areas on the surface or detection chamber are treated with said specific binding reagent and others are not in a recognizable manner (column 10, lines 59-64) such that each of a multiplicity of specific binding reagents of distinct specificity are applied to different areas or regions of a surface or detection chamber of the platform, thereby providing a pattern of distinct specific binding reagents on the platform, including alternating strips, checks, concentric circles, and a "bar code" (column 11, lines 1-25), and wherein there can be multiple detection chambers arrayed serially (column 9, lines 5-7; and Figure 4E). In addition, Sheppard, Jr. et al also teach that the detection system can comprise a component of a device manipulating the platform, preferably comprising an optical detecting means (column 14, lines 61-63) and that the disk can be loaded and spun (column 26, lines 55-56). In addition, Sheppard, Jr. et al also teach the steps of actuating means for positioning a light source on the surface of the platform and having photodetectors to optimally detect optical absorbance/transmittance or other optical signals, which are processed and translated into data including the number of cells on the platform (column 21, lines 57-67), and wherein the device can also be provided

having an interface with an integrated computer having image-processing features (column 31, lines 31-39).

Although Sheppard, Jr. et al reference does not explicitly teach rotating the disc so as to separate different cell types into different capture zones, the instant reference teaches the instant limitation by disclosing disc rotation and a series of binding reagent arrangements, as stated above. The instant reference discloses a multiplicity of specific binding reagents in different areas of a detection chamber, the arrangement of a "bar code" or concentric circles in a detection chamber, and the placement of multiple detection chambers in a serial array. Since Sheppard, Jr. et al reference teaches the rotation of the disc, centrifugal force would move sample fluid in a serial fashion, causing the fluid to enter the serially arrayed detection chambers in a sequential manner. Multiple cell types in a fluid sample would be captured by different specific binding reagents in different regions of the disc, either in separate detection chambers, or in different regions of the "bar code" or concentric circles within a detection chamber, thereby separating different cell types into different capture zones.

However, Sheppard, Jr. et al reference fails to teach that the output includes counts for CD4 and CD8 cells.

Sizto et al reference discloses determining the number of cells, including CD4 and CD8 antigens, and obtaining CD4/CD T-cell ratios (column 6, lines 17-33), in order to determine the presence of cells within a particular subclass per unit volume in a sample, and in determining the progression of AIDS.

It would have been obvious to modify the method of Sheppard, Jr. et al with determining the number of cells, including CD4 and CD8 antigens, and obtaining CD4/CD T-cell ratios, as taught by Sizto et al, in order to determine the presence of cells within a particular subclass per unit volume in a sample, and in determining the progression of AIDS. One of ordinary skill in the art at the time of the invention would have had reasonable expectation of success in detecting CD4 and CD8 cells, as taught by Sizto et al, in the method of Sheppard, Jr. et al, since Sheppard, Jr. et al teach the detection and quantification of cells, and determining the number of CD4 and CD8 cells is one example of detecting and quantifying cells.

In regards to claim 2, Sheppard, Jr. et al teach that the chamber is internal to the disc and is bounded on opposite sides by a substrate and cap, by disclosing that the platform surface is internal to the disc and is enclosed by a top layer (cap) and a bottom layer (substrate) (Figures 5A-E). In reference to the figures, the focus of the light from the light source 54 is on the surface of the chamber where the cells are located (column 14, lines 39-58), and therefore the surface can be considered as part of the substrate, indicated above as the bottom layer. The top layer can be considered a cap since it is superior to the chamber space and opposite the substrate.

In regards to claim 3, Sheppard, Jr. et al teach that the optical disc is constructed with a reflective layer such that light directed to the capture zone and not striking a cell is reflected, by disclosing that platforms can comprise a reflective surface and the detector and the light source are positioned on the same side of the platform (column 24, lines 28-31). A reflective surface inherently reflects light if the light is not attenuated

or absorbed by a substance, including a cell. Therefore, although the reference does not teach the method where light directed to the capture zone and not striking a cell is reflected, one of ordinary skill in the art would recognize that a reflective surface will reflect light that is not attenuated or absorbed.

In regards to claim 4, Sheppard, Jr. et al teach that the optical disc is constructed such that light directed to the capture zone and not striking a cell is transmitted through the optical disc, the disc being between the light source and a detector, by disclosing that platforms can comprise an optically transparent surface that permits a direct light path through the surface of the platform, wherein the light source and detector are positioned on opposite sides of the platform (column 24, lines 20-26). A transparent surface inherently transmits light through the surface if the light is not attenuated or absorbed by a substance, including a cell. Therefore, although the reference does not teach the method where light directed to the capture zone and not striking a cell is transmitted, one of ordinary skill in the art would recognize that a transparent surface will transmit light that is not attenuated or absorbed.

In regards to claim 5, Sheppard, Jr. et al teach that the disc surface is coated with a first group of cell capture agents, by disclosing specific binding reagents comprising a first member of a specific binding pair is provided coating a surface or detection chamber of a platform (column 10, lines 46-48).

In regards to claim 6, Sheppard, Jr. et al teach that the cell capture agents define a capture zone, by disclosing that the surface or detection chamber can be treated to provide a two-dimensional array or pattern, wherein certain areas on the surface or

detection chamber are treated with a specific binding reagent and others (column 10, lines 60-63).

In regards to claim 7, Sheppard, Jr. et al teach that a second group of cell capture agents define a second capture zone, by disclosing that each of a multiplicity of specific binding reagents of distinct specificity are applied to different areas or regions of a surface or detection chamber of a platform, thereby providing a pattern of such distinct specific binding reagents on the platform (column 11, lines 5-9).

In regards to claim 8, Sheppard, Jr. et al teach that the first and second capture zones are in one chamber, by disclosing a multiplicity of specific binding reagents of distinct specificity are applied to different areas or regions of a surface or detection chamber (column 11, lines 5-7).

In regards to claim 9, Sheppard, Jr. et al teach that the cell capture agents are for binding with cell surface antigen, by disclosing that specific binding reagents coated to a surface or detection chamber of a platform is intended to detect a cell expressing a cognate antigen (column 10, lines 45-50).

In regards to claim 12, Sheppard, Jr. et al teach directing the sample of cells into proximity with the cell capture agents, incubating the cells in the presence of the capture agents, and allowing the cells to specifically bind to the capture agents, by disclosing that the sample is driven into a binding/detection chamber and contacts the surface coated with the specific binding reagent, wherein the sample is incubated in the chamber, and wherein the cells are bound to the chamber (allowing cells to bind to capture agents) (column 34, lines 29-45).

In regards to claim 13, Sheppard, Jr. et al teach further including analyzing the number of cells captured to thereby determine a cell concentration in the sample, by disclosing visually observing the number of cells bound to the chamber (column 34, lines 44-45).

In regards to claim 14, Sheppard, Jr. et al teach the analyzing includes detecting sufficiently large changes in a level of light reflected from or transmitted through the disc, by disclosing that particles adsorbed to the surface of the waveguide will both scatter and absorb light, and that the amount of radiation transmitted to the detector that is depressed relative to clean waveguides can be used to infer the number of adsorbed particles (column 23, lines 15-20).

In regards to claims 15, 21 and 31, Sheppard, Jr. et al teach that the analyzing includes using image recognition to count captured cells (claims 15 and 31) and further counting captured cells in each of the capture zones and providing an output including the counts (claim 21), by disclosing that visual inspection of the reaction chamber can be used to resolve cells by a computer-aided vision system (column 32, lines 30-35) and that preferred embodiments include detecting and quantitating individual particles, preferably cells (column 32, lines 40-43).

In regards to claim 17, Sheppard, Jr. et al teach that the chamber has a plurality of capture zones, each having a different cell capture agent, by disclosing that arrays can be discrete arrays each comprising a different specific binding reagent (column 11, lines 9-12).

In regards to claim 18, Sheppard et al teach the rotating includes rotating for a sufficient period of time at a sufficient speed so that the cells have an opportunity to bind with capture molecules, by disclosing that the rotation speed of the invention is increased to drive a milk sample into the binding/detection chamber, where it contacts the surface coated with the specific binding reagent and the sample is incubated in the chamber for 30 minutes (column 34, lines 29-32). In addition, since Sheppard et al teach that following incubation, the rotation rate is "increased", which inherently implies that there was rotation during the incubation period and therefore, the rotation period during the 30 minutes incubation was to apply a sufficient period of time at a sufficient speed so that the cells have an opportunity to bind with the capture molecules.

In regards to claims 19-20, Sheppard, Jr. et al reference teaches that the rotating includes rotating for a sufficient period of time at a sufficient speed so that unbound cells are moved away from the capture zones (claim 19) and wherein the rotating is done at a single speed (claim 20), by disclosing the step of increasing the rotation rate after incubation so that a wash buffer flushes the milk sample out of the chamber and into the waste receptacle (column 34, lines 32-37). Although Sheppard, Jr. et al reference does not explicitly teach the limitations of the instant claims, a certain time period of rotation is obviously required in order to completely remove unwanted materials, including unbound cells, from the capture zone since instantaneous removal is not technically possible. In order to retain only bound cells for analysis, it is therefore necessary to rotate the disc at a certain speed for a "sufficient period of time" and this step would have been obvious and well known to a person of ordinary skill in the art at

the time of the invention. In addition, a high rate of rotation would be effective in removing all liquid samples, including unbound cells from the capture zones. This method of applying centrifugal force is well known to those of ordinary skill in the art at the time of the invention. If the rotation were performed at a single rate high enough to remove liquids of any viscosity, it would be sufficient to remove unbound cells from the capture zone. Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to perform the rotation at a single speed in order to remove all unbound cells away from the capture zone, provided that the speed is high enough to overcome resistance by the viscosity of the liquid.

In regards to claim 22, Sizto et al reference teaches that the output includes a ratio of CD4 and CD8 cells, by disclosing obtaining CD4/CD T-cell ratios (column 6, lines 17-33), as stated above.

In regards to claim 30, Sheppard, Jr. et al reference teaches that the analyzing includes detecting sufficiently large changes in the level of light transmitted through the disc, by disclosing that the intensity of the transmitted light is related to the concentration of the light-scattered particles in a sample (column 24, lines 50-54).

7. Claims 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sheppard, Jr. et al (USP 6,143,247) in view of Sizto et al (USP 5, 962, 238), as applied to claims 1-5 and 9 above, and further in view of Chupp et al (USP 5,812, 419).

Sheppard, Jr. et al and Sizto et al references have been disclosed above, but fail to teach that the cell surface antigens are CD3, CD4, CD8, and CD45.

Chupp et al teach a method of analyzing a blood sample to detect the presence of white blood cells with CD3 and CD8 antigen markers (columns 69-70, Example 6B), and white blood cells with CD4 and CD45 antigen markers (columns 68-69, Example 6A), in order to measure the fraction of lymphocytes that are T Suppressor cells and T Helper cells, respectively.

It would have been obvious to one of ordinary skill in the art at the time of the invention to include in the method of Sheppard, Jr. et al, analyzing a blood sample to detect the presence of white blood cells with CD3 and CD8 antigen markers, and white blood cells with CD4 and CD45 antigen markers, as taught by Chupp et al, in order to measure a fraction of lymphocytes that are T Suppressor cells and T Helper cells, respectively. One of ordinary skill in the art at the time of the invention would have reasonable expectation of success in detecting white blood cells with cell surface antigens CD3, CD4, CD8, and CD45, as taught by Chupp et al, in the method of Sheppard, Jr. et al and Sizto et al, since Sheppard, Jr. et al and Sizto et al teach the detecting and quantifying cells, and white blood cells with CD3, CD4, CD8, and CD45 are types of cells.

8. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sheppard, Jr. et al (USP 6,143,247) in view of Sizto et al (USP 5, 962, 238), as applied to claims 1 and 12-15 above, and further in view of Miller et al (USP 4,307,367).

Sheppard et al and Sizto et al references have been disclosed above, but fail to teach the method of using image recognition to distinguish one type of white blood cell from another.

Miller et al teach that pattern recognition can be used to determine a white blood cell differential count which detects cell types (column 1, lines 25-29), in order to determine the health of a person whose blood sample is being examined.

It would have been obvious to one of ordinary skill in the art at the time of the invention to include in the method of Sheppard, Jr. et al and Sizto et al, the method of using image recognition to determine a white blood cell differential count which detects cell types, as taught by Miller et al, in order to determine the health of a person whose blood sample is being examined. One of ordinary skill in the art at the time of the invention would have reasonable expectation of success in using image recognition to determine a while blood cell differential count, as taught by Miller et al, in the method of Sheppard, Jr. et al and Sizto et al, since Sheppard, Jr. et al and Sizto et al teach that computers with image processing and a computer-aided vision system can be used to resolve cells, and the pattern recognition taught by Miller et al is one example of image processing.

Double Patenting

1. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to

identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

9. Claims 1-22 and 30-31 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2-11 of copending Application No. 10/230,959 in view of Sheppard, Jr. et al (USP 6,143,247) and Sizto et al (USP 5, 962, 238).

Claims 1-22 and 30-31of the instant application disclose a method of conducting an assay, the method comprising providing a sample of cells in a chamber in a disc, the chamber including at least one capture zone with a capture agent, loading the disc into an optical reader, rotating the disc so as to separate different cell types into different capture zones, directing an incident beam of electromagnetic radiation to the capture zone, detecting a beam of electromagnetic radiation formed after interacting with the disc as the capture zone, converting the detected beam into an output signal, and analyzing the output signal to extract therefrom information relating to the number of cells captured at the capture zone, counting captured cells in each of the capture zones, and providing an output including the counts, wherein the output includes counts for CD4 cells and CD8 cells.

Claims 2-11 of the copending application disclose all of the limitations of the instant application with the exception of rotating the disc so as to separate different cell

types into different capture zones, counting captured cells in each of the capture zones, and providing an output including the counts, wherein the output includes counts for CD4 cells and CD8 cells.

Sheppard, Jr. et al reference teaches a platform with detection chambers that can be arrayed serially with a pattern of distinct specific binding reagents therein, including concentric circles and "bar codes", wherein the platform can be spun, and wherein the number of cells on the platform can be processed (column 11, lines 1-25; column 21, lines 57-67; and column 26, lines 55-56), in order to identify particular cells or cell types in a biological sample (Example 1).

Although Sheppard, Jr. et al reference does not explicitly teach rotating the disc so as to separate different cell types into different capture zones, the instant reference teaches the instant limitation by disclosing disc rotation and a series of binding reagent arrangements, as stated above. The instant reference discloses a multiplicity of specific binding reagents in different areas of a detection chamber, the arrangement of a "bar code" or concentric circles in a detection chamber, and the placement of multiple detection chambers in a serial array. Since Sheppard, Jr. et al reference teaches the rotation of the disc, centrifugal force would move sample fluid in a serial fashion, causing the fluid to enter the serially arrayed detection chambers in a sequential manner. Multiple cell types in a fluid sample would be captured by different specific binding reagents in different regions of the disc, either in separate detection chambers, or in different regions of the "bar code" or concentric circles within a detection chamber, thereby separating different cell types into different capture zones.

Sizto et al reference discloses determining the number of cells, including CD4 and CD8 antigens, and obtaining CD4/CD T-cell ratios (column 6, lines 17-33), in order to determine the presence of cells within a particular subclass per unit volume in a sample, and in determining the progression of AIDS.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of the copending application with a platform with detection chambers that can be arrayed serially with a pattern of distinct specific binding reagents therein, including concentric circles and "bar codes", wherein the platform can be spun, and wherein the number o f cells on the platform can be processed, as taught by Sheppard, Jr. et al, in order to identify particular cells or cell types in a biological sample, and to modify the method of the copending application with determining the number of cells, including CD4 and CD8 antigens, and obtaining CD4/CD T-cell ratios, as taught by Sizto et al, in order to determine the presence of cells within a particular subclass per unit volume in a sample, and in determining the progression of AIDS. One of ordinary skill in the art at the time of the invention would have reasonable expectation of success in rotating the disc to separate cells, as taught by Sheppard, Jr. et al, and to count CD4 and CD8 cells, as taught by Sizto et al, in the method of the copending application since both the copending application and Sheppard, Jr. et al teach a rotating optical disk for detecting and counting cells, and CD4 and CD8 cells taught by Sizto et al are examples of cells that can be detected.

This is a provisional obviousness-type double patenting rejection.

10. Claims 2-10 and 13-45 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2-10 and 13-45 of copending Application No. 10/233,322 in view of Sheppard, Jr. et al (USP 6,143,247) and Sizto et al (USP 5, 962, 238).

Claims 1-22 and 30-31 of the instant application disclose a method of conducting an assay, the method comprising providing a sample of cells in a chamber in a disc, the chamber including at least one capture zone with a capture agent, loading the disc into an optical reader, rotating the disc so as to separate different cell types into different capture zones, directing an incident beam of electromagnetic radiation to the capture zone, detecting a beam of electromagnetic radiation formed after interacting with the disc as the capture zone, converting the detected beam into an output signal, and analyzing the output signal to extract therefrom information relating to the number of cells captured at the capture zone, counting captured cells in each of the capture zones, and providing an output including the counts, wherein the output includes counts for CD4 cells and CD8 cells.

Claims 2-10 and 13-45 of the copending application disclose all of the limitations of the instant application with the exception of rotating the disc so as to separate different cell types into different capture zones and providing an output that includes counts for CD4 cells and CD8 cells. The copending application also recites providing a sample of cells on a disc surface in a chamber in a disc, the chamber including capture zone with a capture layer assembly.

Although the instant application does not recite a capture layer assembly, it would have been obvious to one of ordinary skill in the art to recognize that a capture zone requires a layer of capture agents, which includes capture layer assemblies. Since the instant application includes a capture zone with a capture agent, the capture agent would provide a layer on the capture zone and reads on the capture layer assembly recited in the copending application.

Sheppard, Jr. et al reference teaches a platform with detection chambers that can be arrayed serially with a pattern of distinct specific binding reagents therein, including concentric circles and "bar codes", wherein the platform can be spun, and wherein the number o f cells on the platform can be processed (column 11, lines 1-25; column 21, lines 57-67; and column 26, lines 55-56), in order to identify particular cells or cell types in a biological sample (Example 1).

Although Sheppard, Jr. et al reference does not explicitly teach rotating the disc so as to separate different cell types into different capture zones, the instant reference teaches the instant limitation by disclosing disc rotation and a series of binding reagent arrangements, as stated above. The instant reference discloses a multiplicity of specific binding reagents in different areas of a detection chamber, the arrangement of a "bar code" or concentric circles in a detection chamber, and the placement of multiple detection chambers in a serial array. Since Sheppard, Jr. et al reference teaches the rotation of the disc, centrifugal force would move sample fluid in a serial fashion, causing the fluid to enter the serially arrayed detection chambers in a sequential manner. Multiple cell types in a fluid sample would be captured by different specific

binding reagents in different regions of the disc, either in separate detection chambers, or in different regions of the "bar code" or concentric circles within a detection chamber, thereby separating different cell types into different capture zones.

Sizto et al reference discloses determining the number of cells, including CD4 and CD8 antigens, and obtaining CD4/CD T-cell ratios (column 6, lines 17-33), in order to determine the presence of cells within a particular subclass per unit volume in a sample, and in determining the progression of AIDS.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of the copending application with a platform with detection chambers that can be arrayed serially with a pattern of distinct specific binding reagents therein, including concentric circles and "bar codes", wherein the platform can be spun, and wherein the number o f cells on the platform can be processed, as taught by Sheppard, Jr. et al, in order to identify particular cells or cell types in a biological sample, and to modify the method of the copending application with determining the number of cells, including CD4 and CD8 antigens, and obtaining CD4/CD T-cell ratios, as taught by Sizto et al, in order to determine the presence of cells within a particular subclass per unit volume in a sample, and in determining the progression of AIDS. One of ordinary skill in the art at the time of the invention would have reasonable expectation of success in rotating the disc to separate cells, as taught by Sheppard, Jr. et al, and to count CD4 and CD8 cells, as taught by Sizto et al, in the method of the copending application since both the copending application and Sheppard, Jr. et al teach a rotating

optical disk for detecting and counting cells, and CD4 and CD8 cells taught by Sizto et al are examples of cells that can be detected.

This is a provisional obviousness-type double patenting rejection.

Response to Arguments

11. Applicant's arguments filed 21 October 2004 have been fully considered but they are not persuasive.

12. With regards to the limitation of "determining a cell concentration" in claim 13, Applicant states on page 7, lines 13-18 of the Remarks that page 21, line 25- page 22, line 3 of the specification describes the step of determining a cell count and that one of ordinary skill in the art can readily determine a concentration based upon a cell count and a known volume. In addition, Applicant argues that the original claims themselves are part of the original specification and thereby serve as description of the claimed subject matter.

Applicant's arguments are not persuasive because the specification at pages 21-22 does not contain any description of a determining step. It appears that Applicant misunderstood the object. It is not the lack of written description of the method step that is being raised. Instead, MPEP 608.01(o) states that the specification must provide proper antecedent support for terminology used in the claims. In the previous Office Action, the phrase "determining a cell concentration" does not appear anywhere in the

specification. Therefore the specification does not provide antecedent support for these terms and the objection is maintained.

13. Applicants argue on page 8, last paragraph spanning page 9, of the Remarks that the cited prior art fails to teach or suggest all of the claim limitations, and that there is no motivation or suggestion to combine the cited references as cited. Specifically, Applicant contends that the claimed invention is not made obvious by the combination of Sizto et al and Sheppard, Jr. et al references since Sheppard, Jr. et al teaches a system for testing using rotatable disks and Sizto et al teaches a system for scanning that uses scanner that moves longitudinally, and using the scanner of Sizto et al in Sheppard, Jr. et al range would change the principle of operation of the Sheppard, Jr. et al system.

Applicant's arguments are not persuasive because the point of applying Sizto et al reference in combination with Sheppard, Jr. et al is not to combine the scanning systems, as is stated in the 35 USC § 103 rejection supra for claims 1-22 and 30-31. Sheppard, Jr. et al teaches all of the limitations of claim except that "the output includes counts for CD4 cells and CD8 cells". The limitation lacking in Sheppard, Jr. et al does not include any language that involves scanning or the detection apparatus. The cited portions of Sizto et al teach "determining the number of cells, including CD4 and CD8 antigens, and obtaining CD4/CD T-cell ratios", and the motivation to combine with Sheppard, Jr. et al is in order to determine the presence of cells within a particular subclass per unit volume in a sample, and in determining the progression of AIDS.

Sizto et al reference thereby provides teaching and motivation for counting CD4 and CD8 cells, and the steps taught by Sizto et al would work in Sheppard, Jr. et al since Sheppard, Jr. et al teaches that cells can be detected and quantified, and would invariably include the CD4 and CD8 cells taught by Sizto et al.

In addition, since Applicant did not specifically argue and provide reasons why Chupp et al and Miller et al references fail to teach or suggest all of the claim limitations for claims 10-11 and 16, and why there is no motivation or suggestion to combine the references with Sheppard, Jr. et al and Sizto et al, it is the Examiner's understanding that Applicant does not object to the art rejections made in the previous Office Action. Since no additional art has been cited in the instant Office Action, the rejections for claims 10-11 and 16 are therefore maintained and are restated in the 35 USC § 103 rejection supra.

14. With regards to page 10, first paragraph of the Remarks, it is noted that Applicant mentions the provisional double patenting rejections made in the previous Office Action, but does not traverse the rejections with proper arguments. However, since claims in the instant application have been amended, the provisional double patenting rejections made in the previous Office Action are withdrawn in light of the provisional double patenting rejections supra.

Conclusion

15. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

16. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leon Y Lum whose telephone number is (571) 272-2878. The examiner can normally be reached on 8:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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12/20/04